PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CU2002/0020	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CU 03/00002	International filing date *(day/month/year)* 22.01.2003	Priority date *(day/month/year)* 24.01.2002
International Patent Classification (IPC) or both national classification and IPC A61K38/08		
Applicant CENTER FOR GENETIC ENGINEERING AND BIOTECHNILOGY		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03.07.2003	29.03.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Fayos, C Telephone No. +49 89 2399-2180

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CU 03/00002

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-15 as originally filed

Claims, Numbers

1-28 as originally filed

Drawings, Sheets

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1-13, 15-22 (industrial applicability)

   because:

   ☒ the said international application, or the said claims Nos. 1-13, 15-22 (industrial applicability) relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	-
	No:	Claims	1-29
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-29
Industrial applicability (IA)	Yes:	Claims	14, 23-28; 1-13, 15-22 (see separate sheet)
	No:	Claims	-

2. Citations and explanations

see separate sheet

The arguments provided in the letter dated 30.10.03 have been taken into consideration.

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1- Claims 1-13 and 15-22 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

1.1- Claims 1-13 and 15-22 should have been formulated in the "second medical use" format: "Use of X for the manufacture of a medicament for treating / preventing Y".

2- Concerning claims 14 and 23-26 as well as 27-28, it should be noted that a composition is only defined by its components and not by its intended use or alleged effects.

2.1- Only claims formulated in the "second medical use" format are also characterised by the use.

2.2- In the present form, claim 14 merely relates to a GHRP-6 peptide with the sequence: His-D-Trp-Ala-Trp-D-Phe-Lys-NH_2. Claim 27, in the way it is formulated merely relates to a formulation comprising a GHRP-6 peptide with the sequence: His-D-Trp-Ala-Trp-D-Phe-Lys-NH_2.

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

3- Reference is made to the following documents:

D1: ES-A-2 005 224 (EASTMAN KODAK CO) 1 Marzo 1989 (1989-03-01)
D2: US-A-5 767 124 (KAUFMAN MICHAEL J ET AL) 16 Junio 1998 (1998-06-16)
D3: US-A-4 411 890 (MOMANY FRANK A) 25 Octubre 1983 (1983-10-25)

NOVELTY - Art. 33 (1) and (2) PCT

4- Claims 1-28 lack novelty for the following reasons:

4.1- D1 relates to the combination of 2 polypeptides of 3 different groups among which the peptide GHRP-6 His-D-Trp-Ala-Trp-D-Phe-Lys-NH_2 is disclosed (compound number 8938 table 1 p 26) as active agent. In examples 2 and 6, compound 8938 is administered to rats and in example 5 to monkeys, which is active (although less than the combination). The combination is effective in increasing GH liberation in an animal (claim 1 line 24). The invention of D1 is also directed increasing the growth of fishes and crustaceans (p 6 lines 17-18).

Nowhere in D1 it is disclosed that the peptide GHRP-6 His-D-Trp-Ala-Trp-D-Phe-Lys-NH_2 is to be the sole active agent of the formulation; however this is also not apparent from present claim 1.

D1 is therefore novelty destroying for the subject matter of claims 1-28.

4.2- D2 relates to the use of a non-peptide growth hormone secretagogue in food animals to promote their growth. It is mentioned in D2 that growth hormone has the ability of stimulating the immune system.

4.3- D3 does not disclose explicitly the sequence His-D-Trp-Ala-Trp-D-Phe-Lys-NH_2 (see D3 claim 20). However, claims 1, 14 and 27 are directed to a peptide GHRP-6 **with** the sequence His-D-Trp-Ala-Trp-D-Phe-Lys-NH_2, thus implying that said sequence might be included in a much broader sequence, such as that of D3 claim 20 or claim 19. D3 is therefore novelty destroying for the subject matter of claims 14 and 22-28.

INVENTIVE STEP - Art. 33 (1) and (3) PCT

5- Claims 1-28 lack inventive step:

5.1- Should novelty be established, then the subject matter of claims 1-28 would still lack inventive step in view of D1, taken alone or in combination with D2 or D3.

INDUSTRIAL APPLICABILITY - Art. 33 (1) and (4) PCT

6- For the assessment of the present claims 1-13 and 15-22 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.